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| APPLICATION NO.                     | FILING DATE    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------------|----------------|----------------------|---------------------|------------------|
| 09/676,783                          | 10/02/2000     | William J. McBride   | 018733/0997         | 1348             |
|                                     | 590 03/27/2002 |                      |                     |                  |
| Bernhard D. Saxe<br>FOLEY & LARDNER |                |                      | EXAMINER            |                  |
| Washington Ha                       |                |                      | BHATTI, TAHIRA H    |                  |
| Washington, DC 20007-5109           |                |                      | ART UNIT            | PAPER NUMBER     |
|                                     |                |                      | 1607                |                  |

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.   | Applicant(a)  |
|---|---|---|
| •   | _   | Applicant(s)  |
| Office Action Summary   | 09/676,783  | MCBRIDE ET AL.  |
|   | Examiner  | Art Unit  |
| Th MAILING DATE of this communication app   | Tahira H Bhatti   | 1627  |
| Period for Reply  | ears on the cover sheet with the t  | correspond nce address  |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | i6(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) day ill apply and will expire SIX (6) MONTHS from cause the application to become ARANDONE | nely filed s will be considered timely. the mailing date of this communication. |
| Status  |   |   |
| 1) Responsive to communication(s) filed on  | _·  |   |
|   | s action is non-final.  |   |
| 3) Since this application is in condition for allowal closed in accordance with the practice under E  | nce except for formal matters, pr<br>Ex <i>parte Quayle</i> , 1935 C.D. 11, 4   | osecution as to the merits is<br>53 O.G. 213.                                   |
| Disposition of Claims   |   |   |
| 4) Claim(s) 24-44 is/are pending in the application   | 1.  |   |
| 4a) Of the above claim(s) is/are withdraw   | n from consideration.   |   |
| 5) Claim(s) is/are allowed.   | •   |   |
| 6)☐ Claim(s) is/are rejected.   |   |   |
| 7) ☐ Claim(s) is/are objected to.   |   |   |
| 8) Claim(s) <u>24-44</u> are subject to restriction and/or of   | election requirement.   |   |
| Application Papers  |   |   |
| 9) The specification is objected to by the Examiner.  |   |   |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accept   | ed or b)⊡ objected to by the Exan   | niner.  |
| Applicant may not request that any objection to the   | drawing(s) be held in abeyance. Se  | e 37 CFR 1.85(a).   |
| 11)☐ The proposed drawing correction filed oni  | is: a) ☐ approved b) ☐ disapprov  | ed by the Examiner.   |
| If approved, corrected drawings are required in reply   | to this Office action.  |   |
| 12) ☐ The oath or declaration is objected to by the Exam  | miner.  |   |
| Priority under 35 U.S.C. §§ 119 and 120   |   |   |
| 13) Acknowledgment is made of a claim for foreign p   | oriority under 35 U.S.C. § 119(a)-  | ·(d) or (f).  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  |   |   |
| 1. Certified copies of the priority documents I   | nave been received.   |   |
| 2. Certified copies of the priority documents I   | nave been received in Application   | n No  |
| 3. Copies of the certified copies of the priority application from the International Bure.  * See the attached detailed Office action for a list of   | y documents have been received  | in this National Stage  |
| 14) Acknowledgment is made of a claim for domestic  | priority under 35 LLS C & 110(a)  | /to a manufalanal augultusti  |
| a) The translation of the foreign language provision  | sional application has been recei   | ved   |
| 15) Acknowledgment is made of a claim for domestic Attachment(s)  | priority under 35 U.S.C. §§ 120 a   | and/or 121.   |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)   | 5)   Notice of Informal Dat   | PTO-413) Paper No(s)<br>tent Application (PTO-152)                              |
| U.S. Patent and Trademark Office PTO-326 (Rev. 04-01) Office Action   | n Summary   | Part of Paper No. 6   |

### **DETAILED ACTION**

### Status of the claims:

- Claims 1-23 have been cancelled by the applicant's preliminary amendment,
   Dated, 10/2/2000.
- 2. The preliminary amendment added claims 24-44.
- 3. Claims 1-44 are currently pending.
- 4. Please Note: In an effort to enhance communication with our customers and reduce processing time, a dedicated Fax machine is in place to receive your responses. The fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Jyothsna Venkat, Ph.D., Supervisory Patent Examiner at <a href="mailto:iyothsna.venkat@uspto.gov">iyothsna.venkat@uspto.gov</a> or 703-308-2439. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

### Election/Restrictions

- 5. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Claim 24-44 (in part), drawn to a method of treating a tumor by administering a radiolabeled peptide, classified in class 514, subclass 2+.
  - II. Claim 24-44 (in part), drawn to a method of treating an infectious lesion by administering a radiolabeled peptide, classified in class 514, subclass 2+.

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- III. Claim 24-44 (in part), drawn to a method of treating a myocardial infarction by administering a radiolabeled peptide classified in class 514, subclass 2+.
- IV. Claim 24-44, (in part) drawn to a method of treating a clot by administering a radiolabeled peptide classified in class 514, subclass 2+.
- V. Claim 24-44 (in part) drawn to a method of treating an atherosclerotic plaque by administering a radio-labeled peptide, classified in class 514, subclass 2+.
- VI. Claim 24-44 (in part), drawn to a method of treating a normal organ by administering a radiolabeled peptide classified in class 514, subclass 2+.
- VII. Claim 24-44 (in part), drawn to a method of treating a tissue by administering a radiolabeled peptide classified in class 514, subclass 2+.
- 6. Each group (I-VII) is drawn to a separate and distinct invention. The Radiolabeled peptide is used to treat eight (i.e. in groups, 1-VII) distinct and separate diseases. Art anticipating or rendering obvious one group would not anticipate or render obvious the other groups. Each group will support separate patent. Because each disease is different from the other and the method of treatment is different and distinct from the other and is independent and/or distinct invention. Each individual method of treating a distinct diseased condition, would be distinct, because of distinct object, and would require separate and/or divergent manual /computer search, which are separately and individually burdensome.

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- 7. Because these inventions are distinct for the reasons given above:
- a. And have acquired a separate status in the art because of their recognized divergent subject matter as shown by their different classification.
- b. Require different and independent burdensome manual/computer patent and non-patent literature searches, restriction for examination purpose as indicated is proper.

### **ELECTION OF SPECIES**

8. This application contains claims directed to the following patentably distinct species of the claimed invention: Group I- VII are generic to plurality of disclosed patentably distinct species comprises a peptide that consists of a radio-metal binding moiety selected from a group in claim 41 (spec. page 8, line 27 to page 9, line 22), that is patentably distinct species, comprising specific amino acid sequences which encompass a potentially large number of diverse peptide of different sequence (e.g. length and composition). Each peptide is distinct from the other and is independent and/or distinct invention, since a single difference in an amino acid sequence can have a dramatic effect on the function of the proteins. These species are distinct inventions due to their chemical structure and physiological, and biochemical properties, that are capable of separate manufacture and/or use; and each individual compound would use distinct methods steps, would have different object of producing it, and require separate and/or divergent manual /computer search, which are separately and individually burdensome. Therefore an election of species is required as set forth below.

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The applicant is required to elect:

- A single disclosed peptide (i.e. a single sequence ID NO:) that comprises a radio-metal binding moiety, contained in claim 41.
- 10. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
- 12. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species, MPEP § 809.02(a).
- 13. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.
- 14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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# 15. General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Tahira Bhatti whose telephone number is (703) 605-1203. The examiner can normally be reached on Monday to Friday from 8:00 am to 4:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsana Venkat (art unit 1627), can be reached at (703) 308 0570.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (702) 308-0196

Tahira Bhatti (art unit 1627) Feb. 14, 20002.

> DR. JYOTHSNA MEMIKAT PH.D SUPERMETELY PATERT EXCHINER TECHNOLOGY CLITTER 1600



# RESTRICTION ELECTION FACSIMILE TRANSMISSION

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| ART UNIT: 1627   |
| SERIAL NUMBER: 09/676, 783   |
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